

Transmittal Letter To The United States Designated/Elected Office (DO/EO/US) Concerning A Filing Under 35 U.S.C. 371		Attorney Pocket: 27234U U.S. App. No.: 10/571311 Not Yet Assigned
International Application No.: PCT/EP2004/052172	International Filing Date: 15 Sep. 2004 (15.09.2004)	Priority Date Claimed: 16 Sep. 2003 (16.09.2003) US
Title of Invention: USE OF CICLESONIDE FOR THE TREATMENT OF RESPIRATORY DISEASES		
Applicants for DO/EO/US: BETHKE, Thomas; ENGELSTAETTER, Renate; WURST, Wilhelm		
Applicant hereby submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 USC 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)): <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> A English translation of the International Application as filed (35 U.S.C. 371(c)(2)).</li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not transmitted by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol>		
<b>ITEMS 11 to 20 BELOW CONCERN OTHER DOCUMENT(S) OR INFORMATION INCLUDED:</b>		
<ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input checked="" type="checkbox"/> A <b>FIRST</b> preliminary amendment.</li> <li>14. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter2 and 35 USC 1821 - 1825</li> <li>18. <input type="checkbox"/> A second copy of the published international application under 35 USC 154(d)(4)</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 USC 154(d)(4)</li> </ol>		

U.S. Application No. <b>10/571311</b> Not Yet Assigned	International Application No.: PCT/EP2004/052172	Attorney Docket: 27234U																
20. <input checked="" type="checkbox"/> Other items or information: TRANSMITTAL LETTER; APPLICATION DATA SHEET; INTERNATIONAL PUBLICATION NUMBER: WO 2005/025578 A1, WITH PCT/ISA/210 (INTERNATIONAL SEARCH REPORT); INTERNATIONAL PUBLICATION DATE: 24 MARCH 2005 (24.03.2005), WHICH CONSISTS OF 14 PAGES: 1 PAGE FOR THE COVER SHEET, WITH ABSTRACT, 9 PAGES OF TEXTUAL SPECIFICATION, 4 PAGES OF 42 CLAIMS, 0 SHEETS OF DRAWINGS; <b>PRELIMINARY AMENDMENT TO BE EXAMINED</b> ; EXECUTED DECLARATION AND POWER OF ATTORNEY; PCT/ISA/237 (WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY); PCT/IB/304 (NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT); PCT/IB/308 (FIRST NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION); PCT/IB/308 (SECOND AND SUPPLEMENTARY NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION); PCT/RO/101 (PCT REQUEST); POSTCARD FOR EARLY NOTIFICATION OF THE SERIAL NUMBER REQUEST.																		
The following fees are submitted:																		
21. <input checked="" type="checkbox"/> Basic National Fee (37 CFR 1.492(a))..... \$ 300.00	<u>CALCULATION</u> \$ 300.00	<u>PTO USE ONLY</u>																
22. <input checked="" type="checkbox"/> Examination Fee (37 CFR 1.492 (c)) If the written opinion prepared by ISA/US or the International Preliminary Examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....\$ 0.00 All other situations ..... \$ 200.00	\$ 200.00																	
23. <input checked="" type="checkbox"/> Search Fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International Preliminary Examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$ 0.00 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... \$ 100.00 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB .....\$ 400.00 All other situations ..... \$ 500.00	\$ 400.00																	
<b>Total of 21, 22 and 23</b>																		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding Sequence listing or computer program listing filed in an electronic medium). The fee is \$ 250.00 for each additional 50 sheets of paper or fraction thereof.																		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%;">Total Sheets</th> <th style="width: 20%;">Extra Sheets</th> <th style="width: 20%;"># of each additional 50</th> <th style="width: 20%;">RATE</th> </tr> <tr> <td>23-100 =</td> <td>0/50 =</td> <td>0</td> <td>X \$250</td> </tr> </table>	Total Sheets	Extra Sheets	# of each additional 50	RATE	23-100 =	0/50 =	0	X \$250	\$ 0.00									
Total Sheets	Extra Sheets	# of each additional 50	RATE															
23-100 =	0/50 =	0	X \$250															
Surcharge of \$130.00 for furnishing the oath or declaration later than 20 30 months from the earliest claimed priority date (37 CFR 1.492(e)).																		
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%;">CLAIMS</th> <th style="width: 20%;"># FILED</th> <th style="width: 20%;"># EXTRA</th> <th style="width: 20%;">RATE</th> </tr> <tr> <td>TOTAL</td> <td>23-20=</td> <td>3</td> <td>X \$50</td> </tr> <tr> <td>INDEPENDENT</td> <td>1-3=</td> <td>0</td> <td>X \$200</td> </tr> <tr> <td colspan="3">Multiple dependent claims (if applicable)</td> <td>+ \$360</td> </tr> </table>			CLAIMS	# FILED	# EXTRA	RATE	TOTAL	23-20=	3	X \$50	INDEPENDENT	1-3=	0	X \$200	Multiple dependent claims (if applicable)			+ \$360
CLAIMS	# FILED	# EXTRA	RATE															
TOTAL	23-20=	3	X \$50															
INDEPENDENT	1-3=	0	X \$200															
Multiple dependent claims (if applicable)			+ \$360															
<b>TOTAL OF ABOVE CALCULATIONS =</b>																		
<b>\$ 1,050.00</b>																		
Applicant claims small entity status. Fees above are reduced by 1/2.																		
<b>SUBTOTAL =</b>																		
<b>\$ 1,050.00</b>																		
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).																		
<b>TOTAL NATIONAL FEE =</b>																		
<b>\$ 1,050.00</b>																		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +																		
<b>TOTAL FEES ENCLOSED =</b>																		
<b>\$ 1,050.00</b>																		
		Amount to be: refunded \$																
		Amount to be: charged \$																

U.S. Application No.: Not Yet Assigned.	International Application No.: PCT/EP2004/052172	Attorney Docket: 27234U
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10/3/1311

a. ☒ A check in the amount of \$ 1,050.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account Number: 14-0112 in the amount of \$ \_\_\_\_\_ to cover the above fees. (A duplicate copy of this sheet is enclosed.)

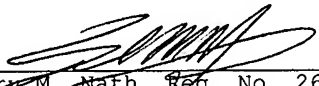
c. ☒ The Commissioner is hereby authorized to charge any additional fees, which may be required, or credit any overpayment to Deposit Account Number: 14-0112.

d. ☐ Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit Card Information should not be included on this form. Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed to request that the application be restored to pending status.

Send All Correspondence To:

7 Gary M. Nath  
NATH & ASSOCIATES PLLC  
112 South West Street,  
Alexandria, VA 22314  
Tel: 1-703-548-6284  
Fax: 1-703-683-8396

  
\_\_\_\_\_  
Gary M. Nath, Reg. No. 26,965  
Sheldon M. McGehee, Reg. No. 50,454  
Customer No. 34375

10/571311

MAIL STOP PCT

Attorney Docket: 27234U

Date: March 9, 2006

APR 20 2006 MAR 09 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

BETHKE, et al.

Serial No.: Not Yet Assigned

Filed: March 9, 2006

International Application: PCT/EP2004/052172

International Filing Date: 15 September 2004

Title: **USE OF CICLESONIDE FOR THE TREATMENT OF RESPIRATORY DISEASES**

TRANSMITTAL LETTER

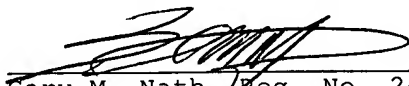
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Application Data Sheet;
- 2) Transmittal Letter to U.S. Designated/Elected Office (DO/EO/US) Concerning Filing Under 35 U.S.C. 371;
- 3) International Publication Number: WO 2005/025578 A1, with PCT/ISA/210 (International Search Report); International Publication Date: 24 March 2005 (24.03.2005), which consists of 14 Pages:
  - 1 page for the Cover Sheet, with Abstract,
  - 9 pages of Textual Specification,
  - 4 pages of 42 Claims,
  - 0 Sheets of Drawings;
- 4) **Preliminary Amendment with Appendices A, B, and C, to be Examined;**
- 5) Executed Declaration and Power Of Attorney;
- 6) PCT/ISA/237 (Written Opinion of the International Searching Authority);
- 7) PCT/IB/304 (Notification Concerning Submission or Transmittal of Priority Document);
- 8) PCT/IB/308 (First Notice Informing the Applicant of the Communication of the International Application);
- 9) PCT/IB/308 (Second and Supplementary Notice Informing the Applicant of the Communication of the International Application);
- 10) PCT/RO/101 (Request);
- 11) Check No.: 1785 in the Amount of \$ 1,050.00 for Basic Filing Fee, which includes the Search and Examination Fees (\$900), and for 3 Extra Total Claims over 20 (\$150), as a Large Entity;
- 12) Postcard for Early Notification of the Serial Number Request.

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

  
Gary M. Nath, Reg. No. 26,965  
Sheldon M. McGee, Reg. No. 50,454  
Customer No. 34375

NATH & ASSOCIATES PLLC  
112 South West Street,  
Alexandria, VA 22314  
GMN/SMM/le